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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/124,280    07/29/98    PORRO    M    576008

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HM12/1005

EXAMINER

RYAN, V

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

10/05/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

09/124,280

07/29/98



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09/124280

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09/124280	07/29/98	HEDMAN GIBSON & COSTIGAN 1185 AVENUE OF THE AMERICAS NEW YORK NY 10036-2601	RYAN, V

EXAMINER
1641

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	5

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-53 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-53 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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## **DETAILED ACTION**

In this application:

Claims 1-53 are pending and under examination.

### ***Drawings***

The drawings are objected to under 37 CFR 1.84 or 1.152 for the reasons stated on PTO 948. Correction is required.

### ***Specification***

The disclosure is objected to because of the following informalities:

Claim 9, line 3 recites "(Lys-Glu)<sub>5</sub>". It appears this should be --(Lys-Asp)<sub>5</sub>--.

Sequences #25, 29, 40 and 41 as recited in the claims do not appear to correspond to the sequences in the Sequence Listing and/or the sequences recited on page 10 of the specification.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 1-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite the terms "of the formula" and "having", respectively. The use of these terms is vague and indefinite because it is unclear if the Applicant intends for this to be open language (i.e., like the use of the word "comprising") or if the Applicant intends for this to be closed language (i.e., like the use of the word "consisting of"). For the following art rejections, the terms "of the formula" and "having" have been interpreted broadly (i.e., similar to the word "comprising").

Claims 11, 17-50 are indefinite in referring to specific amino acid sequences. The sequences depend from claim 1 which indicates that the peptides contain the formula  $(A)_n$ ,  $(AB)_m$  or  $(ABC)_p$ . However, the amino acid sequences listed in the dependent claims do not appear to meet the limitation recited in claim 1.

#### ***Claim Rejections***

***35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

**35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Porro.

Porro (WO 95/03327) disclose a method of administering cationic peptides along with lipopolysaccharide for the treatment

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of bacterial sepsis. (See especially Abstract; page 7, lines 14-20; pages 9-12)

It is noted that the term "vaccine" is viewed as an intended use for the composition.

Therefore, the prior art disclosure is viewed as anticipating the claimed invention.

Claims 1-51 and 53 are rejected under 35 U.S.C. 103 as being obvious by Hancock et al or Velucchi et al in view of Porro.

Hancock et al (US Patent #5,688,767) teach a method of combining cationic peptides and lipopolysaccharide for the treatment of endotoxemia-related disorders. (See especially Abstract; column 23, lines 9-37)

Velucchi et al (Journal of Endotoxin Research 4(4):261-272, 1997) teach a method of detoxifying lipopolysaccharide by treating with cationic peptides. Velucchi et al also teach a method of treating or preventing septic shock by administering the combined elements. (See especially page 2, lines 15-25)

The references, however, differ in not teaching the specific peptides.

Porro (US Patent #5,371,186) teach various cationic peptides which can be used for the treatment of septic shock. Porro also

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teaches several bacterial species which release lipopolysaccharide. (See especially column 1, lines 44-49; column 13, lines 10-20)

The combined teachings of the prior art suggest a method of administering lipopolysaccharide along with cationic peptides in order to treat or prevent septic shock. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to similarly administer the cationic peptides (as taught by Porro) along with lipopolysaccharide for the expected benefit of treating septic shock, absent evidence to the contrary.

Claim 52 is rejected under 35 U.S.C. 103 as being obvious by Porro (WO 95/03327) or Hancock et al in view of the Immunization Practices Advisory Committee.

Porro (WO 95/03327) disclose a method of administering cationic peptides along with lipopolysaccharide for the treatment of bacterial sepsis. (See especially Abstract; page 7, lines 14-20; pages 9-12)

Hancock et al (US Patent #5,688,767) teach a method of combining cationic peptides and lipopolysaccharide for the

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treatment of endotoxemia-related disorders. (See especially Abstract; column 23, lines 9-37)

The references, however, differ in not teaching the administration of the combined lipopolysaccharide and peptide with other vaccine components.

The Immunization Practices Advisory Committee (Clinical Pharmacy 8:839-850, 1989) teach the desirability of administering different antigens at the same time for the convenience of the patient and for preventing multiple diseases. (See especially page 843, last paragraph; page 844, first paragraph)

Given the teachings of the prior art that different antigens can be administered simultaneously, it would have been obvious to one of ordinary skill in the art at the time the invention was made to similarly administer the lipopolysaccharide/peptide vaccine composition with other vaccine components for the art recognized benefit of treating multiple diseases and for the convenience of the patient.

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further



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correspondence regarding this application should be directed to Group Art Unit 1641.

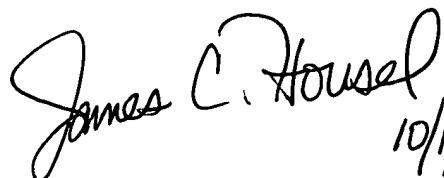
Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan  
Patent Examiner/Art Unit 1641  
September 1999  
Ryan/vr

  
10/1/99  
JAMES C. HOUSEL  
SUPERVISORY PATENT EXAMINER